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PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/619,663
	Filing Date	July 15, 2003
	First Named Inventor	William Howard Roark
	Art Unit	1614
	Examiner Name	Unknown
Total Number of Pages in This Submission	Attorney Docket Number	PC 25207A

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to a Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual	Claude F. Purchase, Jr.
Signature	<i>Claude F. Purchase, Jr.</i>
Date	January 28, 2004

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450 on this date <u>January 28, 2004</u>			
Typed or printed	Nancy Dernbach		
Signature	<i>Nancy Dernbach</i>	Date	January 28, 2004

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USPTO Fax No.



PC25207A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : WILLIAM HOWARD ROARK EXAMINER : UNKNOWN
SERIAL NO. : 10/619,663 ART UNIT : UNKNOWN
FILED : JULY 15, 2003 CONFIRM. NO. : UNKNOWN
FOR : COMBINATION OF AN ALLOSTERIC INHIBITOR
OF MATRIX METALLOPROTEINASE-13 WITH A
SELECTIVE INHIBITOR OF CYCLOOXYGENASE-2 THAT IS
NOT CELECOXIB OR VALDECOXIB

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents
PO BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is an Information Disclosure Statement Under 37 C.F.R. §§ 1.97-1.98
for the above-identified patent application.

Remarks start on page 2.

REMARKS

Claims 1-9 are pending in the application.

The currently pending claims are directed to a combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, a pharmaceutical composition comprising the combination, and a method of treating a disease or disorder using the combination. Applicants' instant paper does not amend the claims.

Information Disclosure Statement

Applicant herein makes available to the Patent and Trademark Office the art cited in the enclosed Information Disclosure Statement ("IDS") on Form(s) PTO/SB/08A and/or PTO/SB/08B. Copies of U.S. patents and patent application publications, if any, cited in the IDS are not provided. Applicant understands that the Patent and Trademark Office has asked that they not be provided in view of their ready availability to the Examiner via electronic means. Copies of all other cited art are provided.

Applicant also makes available to the Patent and Trademark Office the following co-pending applications:

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,174

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX

METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25036A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,777

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR OF MATRIX
METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: 1614

APPLICANT'S DOCKET NO.: PC25131A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,662

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH CELECOXIB OR
VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25132A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,173

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR OF MATRIX
METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25208A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,769

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: 1614

APPLICANT'S DOCKET NO.: PC25209A

The Examiner is respectfully requested to consider carefully the complete text of the cited references in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a), including consideration of the claims.

It is respectfully requested that all cited references considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

The Commissioner is hereby authorized to charge any other fees that may be required, or credit any overpayment, to deposit account number 23-0455.

The undersigned would welcome a telephone call from the Office to discuss any matters.

Respectfully submitted,

Date: January 28, 2004

Claude F. Purchase, Jr.
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Enc.



PTO/SB/08A (08-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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Application Number	10/619,663
Filing Date	July 15, 2003
First Named Inventor	William Howard Roark
Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	PC25207A

Sheet 1 of 7

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 5,948,780	09/07/1999	Peterson, Jr., et al	
		US- 6,008,243	12/28/1999	Bender, et al	
		US- 6,037,361	03/14/2000	Roth, et al	
		US- 6,156,798	12/05/2000	Reiter	
		US- 2002/0019534	02/14/2002	Noe	
		US- 2002/0151555	10/17/2002	Barvian, et al	
		US- 2002/0151558	10/17/2002	Andrianjara, et al	
		US- 2002/0156061	10/24/2002	Barvian, et al	
		US- 2002/0156069	10/24/2002	Picard, et al	
		US- 2002/0161000	10/31/2002	Barvian, et al	
		US- 2002/0193377	12/19/2002	Andrianjara, et al	
		US- 2003/0004172	01/02/2003	Harter, et al	
		US- 2003/0078276	04/24/2003	Andrianjara, et al	
		US- 2003/0130278	07/10/2003	Gaudilliere, et al	
		US- 3,655,679	04/11/1972	Shen, et al.	
		US- 5,521,181	05/28/1996	Meyer, et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

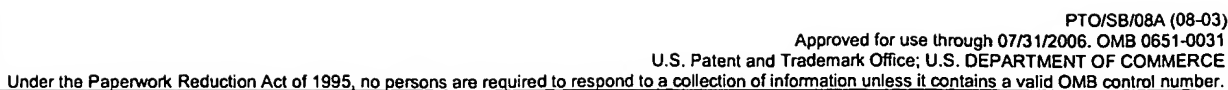
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 02/064572 A1	08/22/2002	Andrianjara, et al		
		WO 02/064595 A1	08/22/2002	Andrianjara, et al		
		WO 02/096426 A1	12/05/2002	Sheppeck, et al		
		WO 02/064568 A1	08/22/2002	Barvian, et al		
		WO 02/064599 A1	08/22/2002	Dyer, et al		
		WO 02/064547 A2	08/22/2002	Barvian, et al		

Examiner Signature	Date Considered
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of 7

Application Number	10/619,663
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First Named Inventor	William Howard Roark
Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	PC25207A

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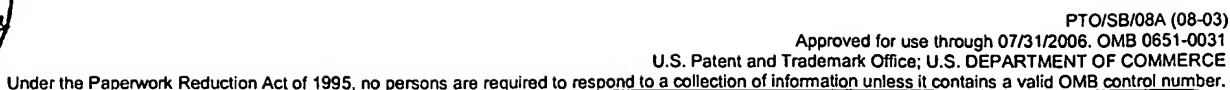
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ^d
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		WO 02/064598 A1	08/22/2002	Harter, et al		
		WO 02/064080 A2	08/22/2002	Andrianjara, et al		
		WO 02/064571 A1	08/22/2002	Barvian, et al		
		WO 03/032999 A1	04/24/2003	Bunker, et al		
		WO 03/033477 A1	04/24/2003	Gaudilliere, et al		
		WO 99/52910	10/21/1999	Robinson		

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of 17

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Attorney Docket Number	PC25207A

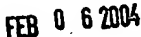
U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
		WO 02/34726	05/02/2002	Noe, et al		
		WO 02/34753	05/02/2002	Bronk, et al		
		EP 1 138 680	10/04/2001	Noe		
		EP 1 088 550 A1	04/04/2001	Sahagan, et al		
		EP 1 291 345 A1	03/12/2003	Sorenson		
		EP 0 935 963 A2	08/18/1999	McClure, et al		

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Sheet 5

of 7

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Application Number	10/619,663
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Art Unit	1614
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Attorney Docket Number	PC25207A

U. S. PATENT DOCUMENTS

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		Country Code ³ *Number ⁴ *Kind Code ⁵ (if known)				
		JP Hei 8-143568 A2	06/04/1996	Hiroko, et al.		<input checked="" type="checkbox"/>
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/619,633		
		Filing Date	July 15, 2003		
		First Named Inventor	William Howard Roark		
		Art Unit	1614		
		Examiner Name	Unknown		
Sheet	6	of	7	Attorney Docket Number	PC25207A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		PCT International Search Report PCT/IB03/03040	
		Weisburger, , et al, "Biochemical Formation and Pharmacological, Toxicological, and Pathological Properties of Hydroxylamines and Hydroxamic Acids", Pharmacological Reviews, 1973, Vol. 25, No. 1; pp 1-66	
		Levin, et al, "The Discovery of Anthranilic Acid-Based MMP Inhibitors. Part 1: SAR of the 3-Position", Bioorganic & Medicinal Chemistry Letters, 11, 2001, pp 235-238; XP004314856	
		Laufer, Stefan, "Was bietet die Zukunft? Neue NSAR", Selektivitätsfaktoren Von Cox-Inhibitoren; Vol. 31, No. 2, 2002; pp 164-169; XP001132092	
		Goldman, et al, "Valdecoxib A Cox-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea", Formulary, Advanstar Communications, Cleveland, OH, US; Vol. 37, No. 2, February 2002; pp 68, 71-74, 76-77; XP008009874	
		Montana, et al, "The design of selective non-substrate-based matrix metalloproteinase inhibitors", Current Opinion in Drug Discovery & Development, 2000; 3(4); pp 353-361	
		Clark, et al, "Matrix metalloproteinase inhibitors in the treatment of arthritis", Current Opinion in Anti-inflammatory & Immunomodulatory Investigational Drugs, 2000; 2(1); pp 16-25	
		Chen, et al, "Structure-Based Design of Novel, Potent, and Selective Inhibitor for MMP-13 Utilizing NMR Spectroscopy and Computer-Aided Molecular Design", J. Am. Chem. Soc., 2000, 122; pp 9648-9654	
		Lovejoy, et al, "Crystal structures of MMP-1 and -13 reveal the structural basis for selectivity of collagenase inhibitors", Nature Structural Biology, Vol. 6, No. 3, March, 1999; pp 217-221	
		Moy, et al, "High-resolution Solution Structure of the Catalytic Fragment of Human Collagenase-3 (MMP-13) Complexed with a Hydroxamic Acid Inhibitor", J. Mol. Biol. (2000) 302; pp 671-689	

Examiner Signature		Date Considered	
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	7	of	7	Attorney Docket Number	PC25207A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Kujundzic, N. et al., "Synthesis of 8-Methyl-1,2,3,4-tetrahydropyrido-[3,4-d]pyrimidine-2,4-diones", Croatia Chemica Acta, 1991;64(4):599-606 (English)	
		Hirota, K. et al., "Novel synthesis of pyrido[3,4-d]pyrimidines, pyrido[2,3-d]pyrimidines, and quinazolines via palladium-catalyzed oxidative coupling", Heterocycles, 1994;37(1):563-570	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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